UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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| AMY LICHT, | * | |
| Plaintiff, | * | |
| v. | * | |
| | * | Civil Action No. 22-cv-10515-ADB |
| MERCK & CO., INC., MERCK SHARP & DOHME CORP., ORGANON & CO., and ORGANON, LLC, | * | |
| Defendants. | * | |

**MEMORANDUM AND ORDER ON DEFENDANTS' MOTION TO DISMISS**

BURROUGHS, D.J.

Plaintiff Amy Licht ("Plaintiff" or "Licht") brings the instant action against Merck & Co., Inc., Merck Sharp & Dohme Corp., Organon & Co., and Organon, LLC (collectively, "Merck" or "Defendants") for claims arising from neuropsychiatric injuries allegedly incurred after ingesting the prescription pharmaceutical product, Singulair. Before the Court is Merck's motion to dismiss Count I and Count III, insofar as Count III states a claim for negligent design. [ECF No. 13]. For the following reasons, the motion is GRANTED.

## I. BACKGROUND

### A. Factual Background

The following facts are taken primarily from the complaint, [ECF No. 2-1 ("Compl.")]. The Court assumes the factual allegations in the complaint to be true when considering a motion to dismiss. Ruivo v. Wells Fargo Bank, N.A., 766 F.3d 87, 90 (1st Cir. 2014).

Merck began selling the prescription drug Singulair in 1998. [Compl. ¶ 2]. The active ingredient in Singular is montelukast, the anti-asthmatic properties of which Merck discovered and subsequently patented in 1996.[1] [Id. ¶¶ 2, 27, 53]. When Merck's patent and its exclusive right to sell the drug expired in 2012, the FDA approved multiple generic forms of Singulair, although Merck continued to manufacture and sell the branded version. [Id. ¶¶ 27, 86].

In 1998, when Merck began selling Singulair, it did not include any warnings about the drug's possible effects on the brain. [Compl. ¶ 53]. Licht contends that montelukast causes adverse neuropsychiatric events as a result of its ability to cross the blood-brain barrier and accumulate in the central nervous system. [Id. ¶¶ 32, 38, 39]. She further alleges that "Merck knew that Singulair crosses the blood-brain barrier from pre-clinical trials" and that "Merck Defendants misled the FDA" about the amount of the drug detected in the brain. [Id. ¶¶ 51–52]. In the years following Singulair's initial FDA approval, Merck made several changes and additions to Singulair's label that, over time, communicated an ever-higher degree of risk associated with ingesting the medication. [Id. ¶¶ 54–78].

In 2001, Defendants added to Singulair's label a warning that "'dream abnormalities and hallucinations, drowsiness, irritability, agitation including aggressive behavior, restlessness [and] insomnia' have been observed." [Compl. ¶ 54 (alteration in original)]. At another unspecified point, Merck also "added the term 'suicide'" to the label and replaced the previously added term "psychomotor hyperactivity" with "anxiousness." [Id. ¶¶ 59, 61]. And in 2010, "disorientation" was added to the warnings, precautions, and adverse events section of the label. [Id. ¶ 69]. In

[1] "Active ingredient" is defined by the U.S. Food & Drug Administration ("FDA") to mean "any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals." Drugs@FDA Glossary of Terms, FDA (Nov. 14, 2017), https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms.

2017, a collection of patient advisory organizations petitioned the FDA to require Singulair's label to include stronger warnings about neuropsychiatric events. [Id. ¶ 75]. FDA committees ultimately held a hearing on the petition in 2019 after which they required Merck to add a "black box warning"[2] to Singulair's label. [Id. ¶¶ 76–77].

Licht was prescribed and took Singulair from 2008 to 2012, during which time her prescriptions were filled with branded Singulair.[3] [Compl. ¶ 8]. She alleges that "[a]s a direct and proximate result of ingesting Singulair, [she] suffered neuropsychiatric injury including depression, anxiety and [obsessive compulsive disorder]." [Id.].

In the present suit, Licht brings counts against Defendants that relate to her use of branded Singulair and generic equivalents. [Compl. ¶¶ 106–215]. She asserts that Defendants, as the brand-name manufacturer of the drug, "controlled the contents of the Singulair label as well as the labels on the generic equivalents of Singulair[,]" [id. ¶ 192], because manufacturers of the generics "have only the duty to ensure their labels for generic bioequivalent to Singulair are the same as the label used by the brand[,]" [id. ¶ 88]. Therefore, Licht argues, Defendants "knew that any deficiencies in the label . . . would be perpetuated in the label of its generic bioequivalent." [Id. ¶ 89].

Licht further argues that because of information obtained through "post-marketing information[,] . . . reanalysis of existing data and scientific literature[,] . . . reanalysis of preclinic

[2] "Boxed warnings (formerly known as Black Box Warnings) are the highest safety-related warning that medications can have assigned by the [FDA]. These warnings are intended to bring the consumer's attention to the major risks of the drug." Claire Delong and Charles V. Preuss, Black Box Warning, STATPEARLS (June 23, 2022), https://www.ncbi.nlm.nih.gov/books/NBK538521/.

[3] Licht states that she also took a generic version of Singulair but does not say when that occurred. [Id. ¶ 193].

and clinical trials[,] . . . the increasing body of publicly available scientific literature regarding montelukast[,] . . . [and] post-marketing surveillance information available to the Merck Defendants[,]" the revisions to Singulair's label should have come earlier and been more pronounced. [Id. ¶¶ 79–82]. She further claims that if she had known about the "defects in Singulair, [she] would not have taken [it]" and instead "would have taken a safer alternative . . . that would not have exposed [her] to neuropsychiatric events." [Id. ¶ 143].[4]

**B. Procedural Background**

Licht filed her five-count complaint against Merck in Bristol Superior Court on March 3, 2022 alleging design defect strict liability (Count I), failure to warn (Count II), negligence (Count III), misrepresentation (Count IV), and breach of express warranty (Count V). [Compl. ¶¶ 106–215]. On April 7, 2022, Merck removed the action to this Court, [ECF No. 1], and then on April 14 moved to dismiss Count I and Count III, insofar as Count III states a claim for negligent design, [ECF No. 13]. Plaintiff filed an opposition, [ECF No. 21], and Defendants replied, [ECF No. 24].

## II. LEGAL STANDARD

In reviewing a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the Court must accept as true all well-pleaded facts, analyze those facts in the light most favorable to the plaintiff, and draw all reasonable factual inferences in the plaintiff's favor. See Gilbert v. City of Chicopee, 915 F.3d 74, 76, 80 (1st Cir. 2019). "[D]etailed factual allegations" are not required, but the complaint must set forth "more than labels and conclusions." Bell Atl. Corp. v.

[4] Licht notes that many alternative medications existed that her doctor could have prescribed as an alternative to Singulair, "including other leukotriene receptor antagonists, inhaled corticosteroids, antihistamines, and a host of other pharmaceutical and non-pharmaceutical options . . . ." [Compl. ¶ 114].

Twombly, 550 U.S. 544, 555 (2007). The alleged facts must be sufficient to "state a claim to relief that is plausible on its face." Id. at 570.

"To cross the plausibility threshold a claim does not need to be probable, but it must give rise to more than a mere possibility of liability." Grajales v. P.R. Ports Auth., 682 F.3d 40, 44–45 (1st Cir. 2012) (citing Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). "A determination of plausibility is 'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" Id. at 44 (quoting Iqbal, 556 U.S. at 679). "[T]he complaint should be read as a whole, not parsed piece by piece to determine whether each allegation, in isolation, is plausible." Hernandez-Cuevas v. Taylor, 723 F.3d 91, 103 (1st Cir. 2013) (quoting Ocasio-Hernández v. Fortuño-Burset, 640 F.3d 1, 14 (1st Cir. 2011)) (further citation omitted). "The plausibility standard invites a two-step pavane." A.G. ex rel. Maddox v. Elsevier, Inc., 732 F.3d 77, 80 (1st Cir. 2013) (citing Grajales, 682 F.3d at 45). First, the court "must separate the complaint's factual allegations (which must be accepted as true) from its conclusory legal allegations (which need not be credited)." Id. (quoting Morales-Cruz v. Univ. of P.R., 676 F.3d 220, 224 (1st Cir. 2012)). Second, "the court must determine whether the remaining factual content allows a 'reasonable inference that the defendant is liable for the misconduct alleged.'" Id. (quoting Morales-Cruz, 676 F.3d at 224) (internal quotation marks omitted).

## III. DISCUSSION

As stated above, Defendants have moved to dismiss Count I and Count III, to the extent that Count III alleges negligent design, arguing that design defect claims are not recognized in the Commonwealth and, alternatively, that the claims are preempted. [ECF No. 14 at 1–2].

The Court takes the arguments out of order and begins with preemption and, consistent with the decisions of other sessions of this Court, finds that Plaintiff's design defect claims are

preempted. See e.g., Ortega v. Merck & Co., No. 22-cv-10511-NMG, 2023 WL 35358 (D. Mass. Jan. 4, 2023) (dismissing Singulair design defect claims in a largely similar complaint); Baiona v. Merck & Co., No. 22-cv-10474-RGS, ECF No. 27 (D. Mass. June 2, 2022) (same); Cadorette v. Merck, No. 22-cv-10489-AK, ECF No. 49 (D. Mass. Jan. 27, 2023) (same).

When a medication, like Singulair, has been previously approved by the FDA, any "[m]ajor changes" to the medication "require approval from the FDA prior to implementation, while moderate and minor changes do not." Gustavsen v. Alcon Lab'ys, Inc., 903 F.3d 1, 10 (1st Cir. 2018) (citing 21 C.F.R. § 314.70(b)). Federal regulations provide that "major changes" include modifications in the "qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved [new drug application]." 21 C.F.R. § 314.70(b)(2)(i). Here, Plaintiff alleges that Merk could have made a safer product by either modifying montelukast, Singulair's active ingredient, or modifying Singulair without modifying montelukast such that the drug would be less likely to cross the blood-brain barrier, and therefore be less likely to cause neuropsychiatric events. [Compl. ¶¶ 115, 118–24]. Because such modifications constitute "major changes" to the formulation of Singulair pursuant to 21 C.F.R. § 314.70(b)(2), Defendants could not "lawfully implement such a change without prior FDA approval" and therefore "federal law preempts this cause of action." Ortega, 2023 WL 35358 at *3; see also Baiona, No. 22-cv-10474-RGS, ECF No. 27; Cadorette, No. 22-cv-10489-AK, ECF No. 49. The Court further notes that Plaintiff's arguments regarding what Defendants could have done prior to FDA approval are irrelevant. See Gustavsen v. Alcon Lab'ys, Inc., 272 F. Supp. 3d 241, 255 (D. Mass. 2017) ("It is irrelevant that the defendants could have designed an entirely different product before they sought approval, which may never have been granted.") (citation omitted).

The Court therefore GRANTS Defendants' motion to dismiss Count I (design defect) and Count III (negligence) to the extent that Count III alleges negligent design. Because the Court finds that these claims are preempted, it need not consider Defendants' argument that Plaintiff's design defect claims are not recognized in the Commonwealth.

Plaintiff, in her opposition to Defendant's motion, asked that if the Court dismissed any of her claims, it also grant her leave to amend. [ECF No. 21 at 6]. Rule 15(a)(2) provides that "[t]he court should freely give leave [to amend] when justice so requires[,]" Fed. R. Civ. P. 15(a)(2), but courts may nevertheless deny leave for a variety of reasons including if any such amendment would be futile. United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 48 (1st Cir. 2009) ("Reasons for denying leave include undue delay in filing the motion, bad faith or dilatory motive, repeated failure to cure deficiencies, undue prejudice to the opposing party, and futility of amendment.") (citing Foman v. Davis, 371 U.S. 178, 182 (1962)). Here, the Court finds, in line with other sessions of this Court, that "no prospective amendment to [Plaintiff's] complaint could alter the fact that any claims against defendants concerning the design of Singulair are preempted by federal law." Ortega, 2023 WL 35358 at *3; see also Baiona, No. 22-cv-10474-RGS, ECF No. 27; Cadorette, No. 22-cv-10489-AK, ECF No. 49. The Court therefore DENIES Plaintiff's request for leave to amend.

## IV. CONCLUSION

For the above reasons, the motion to dismiss, [ECF No. 13], is GRANTED and Plaintiff's request for leave to amend is DENIED.

**SO ORDERED.**

January 30, 2023

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE